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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/853,684	05/09/97	DEEN	K

EXAMINER	
DRAPER, G	
ART UNIT	**PAPER NUMBER**
1812	

18N2/1124

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DATE MAILED: 11/24/97

For Restriction and Sequence Compliance

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), ~~or thirty days~~, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-19 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-19 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s) Sequence Compliance (Errors)

☐ Notice of Reference Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☒ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

★ U.S. GPO: 1998-409-290/40029

RESTRICTION REQUIREMENT AND REQUIREMENT FOR SEQUENCE COMPLIANCE

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). A computer readable form (CRF) of the sequence listing was submitted. However, the CRF could not be processed by the Scientific and Technical Information Center (STIC) for the reason(s) set forth on the attached CRF Diskette Problem Report.

Applicant is given ONE MONTH, or THIRTY DAYS, whichever is longer, from the date of this letter within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend the period for response beyond the SIX MONTH statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached CRF Diskette Problem Report with the response.

Applicants initial submission of 5-9-97 with the filing of the application has been found to contain errors. See the attached error listing.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9 , drawn to DNA and method of making the receptor , classified in classes 536 and 435, subclass 23.5 and 69.1.

II. Claims 10-11, drawn to TR6 receptor protein, classified in class 530, subclass 350.

III. Claim 12, drawn to antibody to TR6, classified in class 530, subclass 388.22.

IV. Claim 13(a), drawn to a method of treatment using an agonist, classified in classes 424 or 514, subclass vary depending on the nature and make-up of the agonist.

V. Claims 13(b) and 14(b), drawn to a method of treatment using nucleic acids, classified in class 514, subclass 44.

VI. Claim 14(a), drawn to a method of treatment using an antagonist, classified in classes 424 or 514, subclass vary depending on the nature and make-up of the antagonist.

VII. Claim 14(c), drawn to a method of treatment using the TR6 polypeptide, classified in class 514, subclass 2+.

VIII. Claim 15, drawn to a method of diagnosing for disease, classified in class 435, subclass 6.

IX. Claims 16 and 18 drawn to methods of identifying agonist and antagonist , classified in class 435, subclass 7.1+.

X. Claim 17, drawn to an agonist, classified in classes and subclass which vary depending on the nature and make-up of the agonist.

XI. Claim 19 drawn to an antagonist, classified in classes and subclass which vary depending on the nature and make-up of the antagonist.

The inventions are distinct, each from the other because:

Inventions Group I and Group II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the receptor of Group II can be made by a materially different process other than with the use of the NA, vectors and host cells of Group I such as by chemical synthesis, or the isolation from nature using various isolation/purification/chromatographic procedures. Further, the NA of Group I can be used other than to make the protein of Group II, such it their use as probes, or their use in various diagnostic procedures or in various therapeutic procedures.

Inventions Group II and Group VII or Group III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein can be used in a materially different method such as its use as a probe, or in various diagnostic or other therapeutic methods.

Inventions Group I and Groups V, VIII , or IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids or cells can be used as a probe or in the various diagnostic or therapeutic methods as listed above or to make transgenic animal.

Inventions Group X and Group IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the agonist can be used as a probe or in various therapeutic or diagnostic methods.

Inventions Group XI and Group VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antagonist can be used as a probe or in various therapeutic or diagnostic methods.

It is further pointed out that although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for multiple/different products, restriction is deemed to be proper because the products appear to constitute patentably distinct inventions. The inventive products of Groups I, II, III, X and XI are directed to products that are structurally, physically and functionally distinct and if determined to be patentable they would also

be patentably distinct. Furthermore, these products are not required one for the other nor is each required for each of the methods of Groups I, IV, V, VI, VII, VIII OR IX.

In a similar manner it is further pointed out that although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for multiple/different methods, restriction is deemed to be proper because the methods appear to constitute patentably distinct inventions. The inventive methods of Groups I, IV, V, VI, VII, VIII OR IX. require the use of different steps/methods; elements/agents that are physically and functionally distinct; there are different starting elements and the final outcome/results are different for these different methods that cover various diagnostics and therapeutic methods; and if determined to be patentable they would also be patentably distinct. . Furthermore, these methods are not required one for the other, nor is each required for each of the products of Groups I, II, III, X or XI.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classifications which are not co-extensive. And there are different issues for the search and examination of each group, which would be unduly burdensome, accordingly, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

3. Any inquiry concerning this communication should be directed to Garnette D. Draper at telephone number (703) 308-4232.

GARNETTE D. DRAPER
PRIMARY EXAMINER
GROUP 1800

Flo[redacted]opy Applic[redacted]on No. 08/853684

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 CFR 1.821 - 1.825 for the following reason(s):

☐ 1. This application clearly fails to comply with the requirements of 37 CFR 1.821 - 1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 CFR 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 CFR 1.822 and/or 1.823, as indicated on the attached copy of the marked-up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A substitute computer readable form must be submitted as required by 37 CFR 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 CFR 1.821(e).

☒ 7. Other: See attached error listing

Applicant must provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing"

☐ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification

☐ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d)

For questions regarding compliance with these requirements, please contact:

For Rules Interpretation, call (703) 308-1123
For CRF submission help, call (703) 308-4212
For PatentIn software help, call (703) 557-0400

Please return a copy of this notice with your response.